REMARKS

Entry of the above amendments and reconsideration of this application are requested. Upon entry of the amendments, this application will contain claims 1 and 3-9 and new claims 12-18 pending and under consideration. A single rejection of claims 1 and 3-9 remains, made under the provisions of 35 U.S.C. 103. It is believed that the following remarks and accompanying Declaration of Dr. Michael C. Hiles comprehensively address the rejection. Accordingly, reconsideration and allowance of the application are requested.

As basis for the rejection under 35 U.S.C. 103, the Office Action states at page 2 that claims 1 and 3-9 are "unpatentable over Douglas US Patent 6,090,128 in view of Gregory US Patent 5,990,379". This rejection is traversed because as discussed detail in passages I, II and III below, even if combinable the Douglas and Gregory references fail to suggest the claimed combinations.

I. The Independent Claims

There are two independent claims, claims 1 and 3. Independent claim 1 is directed to a stent graft comprising at least one stent having a proximal end and a distal end and having a lumen extending therethrough between the proximal and distal ends. The stent graft includes a covering of collagen having an isolated extracellular matrix layer that becomes remodeled by host tissue secured to the at least one stent and extending therealong between the proximal and distal ends. As claimed, the covering is a sleeve that initially has a length about equal to twice the length of the at least one stent. A first portion of the sleeve extends along and complements inside surface of the at least one stent, and a second portion of the sleeve is folded back over a proximal end of the at least one stent and then along an outside surface of the at least one stent to the distal end thereof. The first portion and the second portion of the sleeve are secured to at least the distal end of the at least one stent.

Independent claim 3 is directed to a stent graft comprising at least one stent having a proximal end and a distal end and having a lumen extending therethrough between the proximal and distal ends. The stent graft includes a covering of collagen having an isolated extracellular matrix layer that becomes remodeled by host tissue secured to the at least one stent and extending therealong between the proximal and distal ends, wherein the covering is a sleeve that initially has a length about equal to twice the length of the at least one stent. A first portion of the sleeve extends along and complements inside surface of the at least one stent, and a second portion of the sleeve is folded back over a proximal end of the at least one stent and then along an outside surface of the at least one stent to the distal end thereof. The stent graft further comprises a plurality of stents connected together to form a stent frame with lumens of the respective stents coaligned to form a common continuous lumen extending from a distal stent frame end to a proximal stent frame end, and the covering extending therealong between the proximal and distal stent frame ends.

II. The Applicable Law

When rejecting claims under 35 U.S.C. § 103, "the Examiner bears the burden of establishing a *prima facie* case of obviousness based upon the prior art." In re Fritch, 23 U.S.P.Q. 2d 1780, 1783 (Fed. Cir. 1992).[1] To establish a *prima facie* case of obviousness, the Examiner must provide objective evidence 1) of some suggestion or motivation to combine or modify one or more prior art references,[2] 2) that the suggested combination or modification has a reasonable expectation of success,[3] and 3) that the prior art reference or references, when combined, suggest or teach all of applicant's claim limitations. MPEP § 2143. As held by the Federal Circuit, "[t]hese findings or evidence must be specific, clear, and particular." In re Lee, 61 U.S.P.Q. 2d 1430, 1433-34 (Fed.

[1] Citing In re Piasecki and Meyers, 223 U.S.P.Q. 785, 787-88 (Fed. Cir. 1984).

[2] This motivation must be found in the references or within the body of knowledge available to a person of ordinary skill in the art at the time applicant's invention was conceived. See, MPEP § 2142.

[3] "Both the suggestion and the reasonable expectation of success must be founded in the prior art, not in the applicant's disclosure." In re Vaeck, 20 U.S.P.Q. 2d 1438, 1442 (Fed. Cir. 1991) (citing In re Dow Chemical Co., 5 U.S.P.Q. 2d 1529, 1531 (Fed. Cir. 1988)).

Cir. 2002). "Broad conclusory statements regarding the teaching of multiple references, standing alone, are not [considered sufficient] 'evidence'[4]" to support a finding of *prima facie* obviousness. In re Dembiczak, 50 U.S.P.Q. 2d 1614, 1617 (Fed. Cir. 1999); See also, Ex Parte Levengood, 28 U.S.P.Q. 2d 1300, 1301 (Bd. Pat. App. & Int. 1993).

Obviousness determinations must be performed without "entry into the 'tempting but forbidden zone of hindsight.'" Dembiczak, 50 U.S.P.Q. 2d at 1616 (Fed. Cir. 1999).[5] More specifically, in Dembiczak, the Federal Circuit offered the following guidance:

> [m]easuring a claimed invention against the standard established by section 103 requires the oft-difficult but critical step of casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field.[6] . . .

Dembiczak, 50 U.S.P.A. 2d at 1617.[7] The best protection against the use of hindsight is a rigorous application of the motivation to combine criterion, which results in most *prima facie* obviousness determinations hinging on an objective finding of some motivation or suggestion to combine or modify one or more prior art references. See, Dembiczak, 50 U.S.P.Q. 2d at 1617; In re Roufett, 47 U.S.P.Q. 2d 1453, 1457-58 (Fed. Cir. 1998).

In the event the Examiner establishes a *prima facie* case of obviousness, applicants may submit rebuttal evidence to prove that the claim or claims are nonobvious. After rebuttal evidence is submitted, "[r]egardless of whether the *prima facie* case would have been characterized as strong or weak, the examiner must consider all of the evidence anew." In re Piasecki and Meyers, 223 U.S.P.Q. 785, 788 (Fed. Cir. 1984). When evaluating rebuttal evidence, the Examiner must compare the claimed invention as a whole against the prior art references, rather than comparing components of the claimed

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[4] E.g., McElmurry v. Arkansas Power & Light Co., 995 F.2d 1576, 1578, 27 U.S.P.Q. 2d 1129, 1131 (Fed. Cir. 1993) ("Mere denials and conclusory statements, however, are not sufficient to establish a genuine issue of material fact.") [citation omitted].

[5] Quoting Loctite Corp. v. Ultraseal Ltd., 228 U.S.P.Q. 90, 98 (Fed. Cir. 1998) (overruled on other grounds).

[6] [citation omitted].

[7] Citing C.R. Bard, Inc. v. M3 Sys., Inc., 48 U.S.P.Q. 2d 1225, 1232 (Fed. Cir. 1998) (describing "teaching or suggestion or motivation [to combine]" as an "essential evidentiary component of an obviousness holding.")).

invention to the prior art.[8] Additionally, in evaluating the obviousness of a claimed invention, the Examiner must also consider "objective evidence or secondary considerations." MPEP § 2141. For example, advantages directly flowing from the claimed invention are proper support for finding nonobviousness. Preemption Devices, Inc. v. Minn. Mining and Mfg. Co., 221 U.S.P.Q. 841, 844 (Fed. Cir. 1984) (citing Graham et al. v. John Deere Co. of Kan. City, 148 U.S.P.Q. 459 (U.S. 1966)).

III. Analysis Of The Claims And References

1. Claims 1 and 3-9 are Nonobvious Under 35 U.S.C. § 103 (a) Over Douglas (U.S. Pat. No. 6,090,128) in View of Gregory (U.S. Pat. No. 5,990,379).

The stated rejection of claims 1 and 3-9 over the combination of Douglas in view of Gregory fails to establish a *prima facie* case of obviousness. Such a case requires that an Examiner, among other things, provide objective evidence that when combined, the references relied upon suggest or teach all of Applicants' claim limitations. MPEP § 2143. These findings or evidence must be specific, clear and particular. Lee, 61 U.S.P.Q. 2d at 1433-34. Broad conclusory statements regarding the teaching of multiple references are not sufficient. Dembiczak, 50 U.S.P.Q. 2d at 1617. The rejection fails to comply with these standards and is thus improper.

In making this rejection, the Action acknowledged that the primary reference, Douglas, "does not disclose a sleeve made of SIS". Page 3, line 1. After referencing the secondary Gregory reference, the Action bases this rejection upon the assertion that:

> It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the material property of the

[8] "In its argument that the invention here is but making integral what had earlier been made in four bolted pieces, Nortron seeks to limit the focus of inquiry to a structural difference from the prior art and then to show that that difference alone would have been obvious. That effort is not proper under the statute, which requires that an invention be considered 'as a whole' . . . ." Carl Schenck, A.G. v. Nortron Corp., 218 U.S.P.Q. 698, 700 (Fed. Cir. 1983).

Douglas reference with the SIS sleeve of the Gregory reference in order to inhibit the migration of smooth muscle cells in the treated area.

It is respectfully submitted that this is a misinterpretation of the Gregory reference because the Gregory reference does not teach the use of a SIS (small intestinal submucosa) sleeve. Instead, the Gregory reference teaches the use of an elastin-based sleeve and never mentions small intestinal submucosa.

In addition, the Office Action asserts that elements 40, 57, 59 and 61 of the Douglas reference teach the securement of the covering to the distal end of the stent. However, this is also believed not to be the case. Element 40 merely references the "second open end" of tubular body member 32. See, e.g. Col. 7, lines 45-50. Element 57 is a stitch or suture "placed across the diameter of the second end 40 of the hollow tubular body member 32 such that ends 59 and 61 of the suture are left to trail from the second end 40 of the body member 32 in order to aid in deployment of the bifurcated vascular graft 30". See Col. 9, lines 15-20. The use of ends 59 and 61 in deployment is also discussed at Col. 11, lines 47-55. Nowhere is there any teaching that this suture in any way connects the covering of Douglas to a stent. In fact, the deployment views in Fig. 7F (see suture ends) and 7G (no more ends) seem to make it clear that the suture 57 is simply pulled out of the patient after deployment.

For the above reasons, it is believed that the rejection of claims 1 and 3-9 over the combination of Douglas in view of Gregory is not properly supported and should be withdrawn.

Further, independent claims 1 and 3 require the presence of a covering of collagen having an isolated extracellular matrix layer that becomes remodeled by host tissue. When considering the claimed inventions as a whole, the use of a remodelable covering in the claimed configuration provides particular advantages to the stent graft device. When the ends of the claimed covering material are attached at the stent's distal end (see independent claim 1), this means that there is no need for the presence of a circumferential series of sutures as shown in the Gregory reference (a significant foreign body) in the middle of the remodelable material field covering the stent(s). The presence of a midpoint circumferential series of sutures as shown in Gregory can initiate a foreign

body response in that area upon implantation in a patient. As discussed in the accompanying Declaration of Dr. Michael C. Hiles, this foreign body response can deleteriously affect or detract from the healing and remodeling process that is induced by the claimed remodelable covering material. The ability to avoid or minimize foreign body material at the stent's midpoint as enabled by the present invention can lead to more effective tissue ingrowth and remodeling. In addition, in the case of a multiple-stent graft structure (see independent claim 3), the sleeve covering provides the ability to encompass and cover the connected portions of the multiple stents, including any materials such as filaments or other structures used in the connection. Such filaments or other structures present foreign bodies that could interfere with the desired remodeling function of the covering as it contacts bodily lumen surfaces. These factors further buttress the conclusion that claims 1 and 3-9 are not obvious over the applied references.

New claims 12-18 have been added to the application. For at least those reasons discussed above in connection with claims 1 and 3-9, it is submitted that claims 12-18 are not taught or suggested by the combination of Douglas and Gregory set forth in the Office Action. Consideration and allowance of the new claims is thus also solicited.

For the above reasons, the Applicants request withdrawal of the rejection and allowance of this application including claims 1, 3-9 and 12-18. The Examiner is encouraged to contact the undersigned attorney by telephone if there are any matters that can be addressed in that fashion to expedite allowance of this application.

Respectfully Submitted,
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Josef Rosch
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April 3, 2006

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812-330-1824

Enclosure:
Declaration of Dr. Michael C. Hiles
Petition and Fee for Extension of Time